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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 23 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#2F2595 Ronilan on lettuce. Evaluation of residue data and analytical method.

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BASF Wyandotte Corporation proposes a tolerance for the residues of Ronilan [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its 3,5-dichloroaniline containing metabolites on lettuce at 5 ppm.

Tolerances are established for kiwi fruit and strawberries, both at 10 ppm. A proposal of a temporary tolerance for lettuce at 5 ppm was submitted with PP#9F2204. This tolerance has not been established because of deficiencies in the analytical method, and uncertainly as to an appropriate tolerance level.

Conclusions

1a. The nature of the residue in lettuce is adequately understood. The residue of concern consists of the parent and its 3,5-dichloroaniline containing metabolites.

1b. No large animal metabolism studies are available but since no feed items are involved, we will raise no questions concerning the nature of the residue in animals.

2a. The analytical method used for this petition gives control values for lettuce of up to 5.3 ppm. An explanation and/or appropriate revisions of the analytical methodology to reduce these control values will be needed before we can draw a conclusion on the adequacy of the method for enforcement purposes.

3a. The residue data do not support the proposed tolerance. We could recommend for a tolerance of 10 ppm if a 28 day PHI were imposed and this use limited to head lettuce. If use on leaf lettuce is desired then residue data on leaf lettuce will be needed.

3b. However, with the imposition of a 28 day PHI, 3 applications at 14 day intervals will not fit into the growing season of transplanted lettuce (though it would for direct seeded lettuce). The petitioner should revise Section B to limit this use to two applications for transplanted lettuce.

4. Since no feed items are involved there will be no problem of secondary residues in meat, milk, poultry and eggs.

5. An International Residue Limit Status sheet is attached. No Codex MRL's or foreign tolerances are established for Ronilan.

Recommendation

We recommend against the proposed tolerance. For a favorable recommendation we require the following:

1. An explanation of the high check values for Ronilan and/or appropriate revisions to the analytical methodology to reduce the check values.

2. A revised Section F in which a tolerance of 10 ppm is proposed for head lettuce.

3. A revised Section B in which label restrictions limiting this use to head lettuce and establishing a 28 day PHI are imposed. The proposed use should also be changed to limit this use to two applications per season for transplanted lettuce.

If use on leaf lettuce is desired appropriate residue data will be needed. Also the proposed use will have to be changed so that all applications and the PHI will fit in to the relatively short leaf lettuce growing season.

Detailed Considerations

Manufacture and formulation

The manufacturing process has been described in our review of PP#9F2204 (memo of 7/23/79, M. Nelson). Technical Ronilan is prepared by the reaction [redacted]

Ronilan fungicide (50w) is formulated as a 50% wettable powder. The inerts are cleared under 40 CFR 180. 1001(c).

The technical material is 93% pure. Impurities include a maximum [redacted] We do not expect a residue problem from these impurities.

Proposed Use

For control of sclerotinia "drop" on lettuce Ronilan is to be applied to either direct seeded lettuce or transplanted lettuce up to three times at 14 day intervals a rates of up to 2 lb. product (1 lb. a.i.)/A depending on disease pressure. No more than 3 lb. a.i./A are to be applied per season. The PHI is 14 days.

Nature of the Residue

Radiolabel metabolism studies have been carried out in soil, strawberries and rats (PP#8G2068, memo of 1/19/79, G. Makhijani) and in lettuce and peaches (PP#9G2204, memo of 1/18/80, B. Davis). A summary of the lettuce study follows.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Lettuce was twice treated with 1 lb a.i./A ringlabeled ^{14}C Ronilan. The first application was at the two-three leaf stage, the second 19 days later. Autoradiography suggests uniform translocation of Ronilan throughout the plant within one day of foliar application. Samples were taken for residue analysis 0 to 40 days after application. Analysis of the radioactive residue by TLC, HPLC and GL-MS shows that the major metabolic route is by hydrolytic cleavage of the oxazolidinedione ring and/or loss of the ethenyl moiety.

After 21 days virtually all of the parent material had been oxidized to a polar material most of which contained the dichloroaniline moiety and pectin. Over 85% of the polar residues contained the intact dichloroaniline moiety which could be released by alkaline hydrolysis. Of the 0.22 ppm total radioactive residue 0.19 ppm were measured by the analytical GC-EC method.

We reiterate our previous conclusion (PP#G2204, memo of 1/18/80, B. Davis) that this study adequately demonstrates that the residue of concern in lettuce consists of parent and metabolites containing the 3,5-dichloroaniline moiety.

Analytical Method

The residue method involves alkaline hydrolysis of parent and metabolites to form free 3,5-dichloroaniline. The 3,5-dichloroaniline is removed from the hydrolysis mixture by steam distillation and collected in 1N H_2SO_4. The 3,5-dichloroaniline is separated from the aqueous phase by chloroform extraction at two controlled pH's. After drying, the 3,5-dichloroaniline is derivatized with chloroacetyl chloride. The derivative is dissolved in ethyl acetate then determined by GC using a ^{63}N detector. The residue is reported as parent.

Recovery from lettuce samples fortified with 0.05-5 ppm Ronilan ranged from 81-108% (avg. 93%). Most control values are in the 0.1-0.3 ppm range but values as high as 5.33 ppm are reported. Before we can consider this method adequate, the petitioner should explain the reason for these values or revise the method to reduce the level of the control values.

Residue data

The residue data submitted with this petition were previously submitted with PP#9G2204. The following table summarizes these data:

Location	Variety	Rate (lb a.i./A	No appl.	PHI(days)	Residue(ppm)
CA	Salinas	1.0	2	24	4.82
CA	"	1.0	1	47	0.16
MI	Ithaca	0.5	3	30	1.43
MI	"	1.0	3	30	7.30
NJ	"	1.0	2	56	1.82
NJ	"	1.0	3	49	0.41
NY	"	1.0	3	56	0.05-.0.07
WI	"	1.0	2	27	0.07
NY	"	0.5	5	9	6.15-10.7
NY	"	0.75	5	9	1.07-13.2
OH	Boston	1.0	3	14	1.32
TX	Iceberg	0.75	2	15	0.59-0.74
TX	Great Lake	0.75	2	29	0.49-1.48
CA	Salinas	1.0	1	14	0.59
"	"	"	"	0	60
"	"	"	"	1	48.5
"	"	"	"	3	17.2
"	"	"	"	5	14.6
"	"	"	"	7	7.35
"	"	"	"	11	2.19
"	"	"	"	14	1.42
"	"	"	"	21	0.96
"	"	"	"	24	4.82
NJ	Ithaca	1.0	2	14	1.66
"	"	"	"	0	17.8
"	"	"	"	1	12.3
"	"	"	"	3	8.4
"	"	"	"	5	4.04
"	"	"	"	7	3.40
"	"	"	"	11	2.51
"	"	"	"	14	1.34
"	"	"	"	21	0.88
"	"	"	"	24	0.56
"	"	"	"	35	0.55
"	"	"	"	56	1.82

The submitted data do not support the proposed tolerance. Few studies are representative of the proposed use and no residue data are available for leaf lettuce. However, we could recommend for a 10 ppm tolerance for head lettuce provided a 28 day PHI were imposed and this use was limited to head letuce. For tranplanted lettuce this means that this use must be limited to two applications as 3 applications at 14 day intervals and a 28 day PHI will not fit into the post transplant growing season of lettuce. The petitioner should revise Section B accordingly.

To support a tolerance for lettuce (which would include leaf lettuce), residue data for leaf lettuce will be needed. Any use proposed for leaf, lettuce should be accommodated in the relatively short growing season; the present use (3 applications at 14 day intervals and a 28 day PHI) will not fit into the shorter leaf lettuce growing season.

Meat, Milk Poultry and Eggs

As no feed items are involved, there will be no problem of secondary residues in meat, milk, poultry and eggs.

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